THE NATIONAL CHILDREN'S STUDY

HEALTH GROWTH ENVIRONMENT

The National Children's Study Environmental Methodologies

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Vanguard Study Goals

- Determine feasibility acceptability and cost of:
  - Recruitment strategies
  - Study operations and logistics
  - Study assessments
- Achieved by rigorous objective data driven evaluations of the current protocol procedures
- Testing and evaluation of alternative methods and procedures to improve the efficiency and economy of Study data collection and evaluation, and participant satisfaction

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NCS Vanguard Study Development

THEN

Hundreds of experts

↓

Consensus Building

↓

Construct Assumptions

↓

Modeling

↓

NCS Study Design and Process

NOW

Empiric Data

↓

Analysis with ever tightening confidence intervals

↓

NCS Study Design and Process

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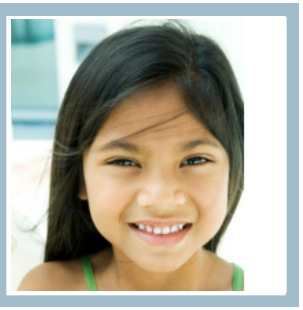
Vanguard Study Evaluation



Consensus Based

- Fixed visit structure and schedule
- Each participant receives each measurement
- Study modifications at fixed intervals

Evidence Based

- Dynamic flexible structure and schedule
- Some participants receive more extensive assessments to collect sufficient quality data for detailed analysis
- Study modifications initiated when evidence indicates change is beneficial

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NCS Challenges

"There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we know we don't know. But there are also unknown unknowns. There are things we don't know we don't know."
Donald Rumsfeld

"A difficulty with conceiving current cohorts both as research resources for now and for many decades into the future is that we cannot imagine what data researchers will require in at least 50 years time. For example, the includes detailed family Aberdeen Children of the 1950s cohort data that describes parental health, interests (including, for example, which newspapers or magazines they subscribed to) as well as perinatal and later childhood data, but has no information on parental smoking."*

*Lawlor, DA et al Internat J Epi 2009;38:897–902

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Study Visit Assessment Evaluation

- Study visit assessment criteria
  - Feasibility, acceptability and cost
  - Reliability , reproducibility
  - Informative value
  - Lack of redundancy
- Ability to address a question that
  - has potentially important public health impact
  - requires a study of NCS size and robustness to answer
  - unlikely to be answered in another context

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Evaluating NCS Cost Drivers

- In general major cost drivers are:
  - Recruitment strategy
  - Number of visits
  - Complexity of each visit
- The resource footprint for each visit as well as study operations is largely a function of the number of personnel involved and the level of effort required for data collection

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Main Study Process Considerations

- Recruitment rate estimates based on Vanguard Study empiric data to reach the accrual target of 100,000
- Main Study cost estimates will be based on study design factors such as:
  - Duration, effort and costs for recruitment
  - Geographic location and resource footprint for each visit. For example, home based visits will have different requirements than clinical based visits
  - Scale up costs of data processing, quality assurance, data archiving and data analysis
  - Number, complexity and costs for outcome assessments
- Additional secular factors such as health care, transportation, data security and other costs will also impact the Main Study cost estimates

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Environmental Science Dynamics

- Existing exposure information is fragmented
  - No uniform terminology or standard methodology
  - Lack of validated exposure measurement and modeling methodology for public health applications
  - No central accessible data bases for exposure data
- Emerging contaminates of concern
- Increasing complexity to estimate exposure in terms of spatial and temporal variability
- Public health consideration for susceptible periods of development and vulnerable population segments

Study Visit Challenges

- Single monitoring design cannot address all of the environmental issues for the NCS
- Study visit measurement methods must be high quality, documented, accessible, and transparent
- Study visit scheduled must be flexible and adaptable to meet the unanticipated future needs of the NCS

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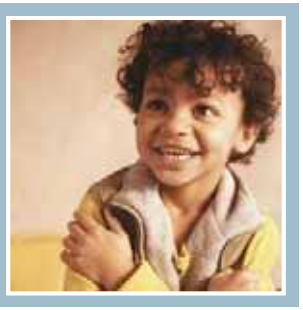
NCS Evaluation Approach

- Metrics based on feasibility, acceptability, and cost to evaluate completed study visits
- Evaluation of measurement method performance
- Evaluation of external consistency via review of existing cohort study results
- Identification of validated measurement methods for consideration for the Main Study
- LOI formative research projects to expand and optimize visit measurement methodology

Future Opportunities



- Develop exposure nomenclature and terminology for longitudinal cohort studies
- Develop data base of environmental exposure instruments used in longitudinal cohort studies
- Conduct validation studies for environmental exposure instruments
- Foster adoption of consensus standards and methodology to assure consistency, scalability, adaptability and interoperability for environmental assessments

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